

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CHAMBERS OF
JOSÉ R. ALMONTE
UNITED STATES MAGISTRATE JUDGE

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February 10, 2023

LETTER ORDER

Re: *Pacira Pharmaceuticals, Inc., et al. v. eVenus Pharmaceuticals
Laboratories, Inc., et al.*,
Case No. 21-cv-19829-MCA-JRA; Case No. 22-cv-00718-MCA-JRA

Dear Counsel:

Defendants eVenus Pharmaceuticals Laboratories, Inc., Jiangsu Hengrui Pharmaceuticals Co., Ltd., and Fresenius Kabi USA, LLC (collectively, “Defendants”), move to amend their Answer (“Motion”). ECF No. 112. Plaintiffs Pacira Pharmaceuticals, Inc., and Pacira Biosciences, Inc. (collectively, “Plaintiffs”), oppose the Motion. The Court has considered the Motion on the papers without oral argument. *See* Fed. R. Civ. P. 78(b); L.Civ.R. 78.1(b). For the reasons discussed below, Defendants’ Motion is **GRANTED**.

BACKGROUND

Plaintiff Pacira Pharmaceuticals is the holder of the New Drug Application No. 022496, under which the United States Food and Drug Administration (“FDA”) approved the commercial marketing of EXPAREL®. Am. Compl. ¶ 57, ECF No. 54. EXPAREL® is a local anesthetic administered to minimize postsurgical pain in patients. *Id.* at ¶ 58. The active ingredient in EXPAREL® is bupivacaine, which is encapsulated in multivesicular liposomes. *Id.* Pacira Pharmaceuticals owns U.S. Patent No. 11,033,495 (the “’495 Patent”), which includes claims for preparing bupivacaine encapsulated in multivesicular liposomes by a commercial scale process. *Id.* at ¶¶ 53-54.

Plaintiffs initiated this action alleging, among other things, that Defendants’ submission of an Abbreviated New Drug Application (“ANDA”) to the FDA requesting approval to manufacture and sell a generic version of EXPAREL® is an act of infringement of the ’495 Patent. *Id.* at ¶¶ 60, 73. In their Answer to the Amended Complaint, Defendants deny Plaintiffs’ claims of infringement and assert counterclaims seeking a declaratory judgment of noninfringement or of invalidity of the ’495 Patent. *See generally* Answer, ECF No. 73.

On January 18, 2022, the Court issued a scheduling order that set December 20, 2022, as the deadline for “[a]mendments to the pleadings or to join other parties with leave of Court.” ECF No. 21 at 1. On May 9, 2022, the Court entered an amended scheduling order modifying many of the original deadlines. ECF No. 86. The deadline to seek amendment of the pleadings, however, was unchanged. *See id.*

Defendants filed their Motion on December 20, 2022, seeking to amend their Answer, affirmative defenses, and counterclaims to add a defense and counterclaim that the asserted patents are unenforceable due to inequitable conduct. ECF Nos. 112, 113. Through the proposed amendments, Defendants argue that: (i) Plaintiffs’ in-house counsel and one or more named inventors withheld material information from and/or made false representations to the United States Patent and Trademark Office (“PTO”) [REDACTED]

[REDACTED] and (iii) Plaintiffs made contradictory statements to the PTO and FDA [REDACTED] ECF No. 113 at 12-15. Defendants claim that the purpose of Plaintiffs’ actions were to “improperly extend the patent exclusivity into the 2040s for Plaintiffs’ primary commercial product, EXPAREL®.” ECF No. 113 at 12-15. Plaintiffs filed their opposition on January 3, 2023. ECF No. 117. Defendants filed a reply in further support of the Motion on January 10, 2023. ECF No. 120.

DISCUSSION

A. Standard for Amendment

The parties disagree as to the applicable standard for analyzing the Motion. Rules 15 and 16 of the Federal Rules of Civil Procedure govern the appropriate standard for the amendment of a pleading. Under Rule 15, a party may amend a pleading once as of right within a proscribed timeframe and, thereafter, may amend its pleading “with the opposing party’s written consent or the court’s leave.” Fed. R. Civ. P. 15(a)(2). The rule also directs courts to “freely give leave” to amend “when justice so requires.” *Id.*

Even that liberal standard has limits, however. The Court may deny leave to amend the pleadings where there is (1) undue delay, (2) bad faith or dilatory motive, (3) undue prejudice, (4) repeated failures to cure deficiencies, or (5) futility of amendment. *Foman v. Davis*, 371 U.S. 178, 182 (1962); *Arthur v. Maersk, Inc.*, 434 F.3d 196, 204 (3d Cir. 2006) (“Leave to amend must generally be granted unless equitable considerations render it otherwise unjust.”).

Under Rule 16, a party must demonstrate “good cause” prior to the Court amending a scheduling order that sets forth a deadline for amending pleadings. Fed. R. Civ. P. 16(b)(4). The Rule 16 standard applies “when a party seeks leave to amend its pleadings after the deadline for amendment has passed, [and requires] the court [to] conduct a threshold ‘good cause’ inquiry . . . prior to conducting an analysis under Rule 15.” *Lee v. Park*, No. 12-cv-7437, 2015 WL 1523066, at *2 (D.N.J. Apr. 2, 2015). Under Rule 16, a determination of “good cause” depends on the diligence of the moving party. *Harbor Laundry Sales, Inc. v. Mayflower Textile Serv. Co.*, No. 09-cv-6259, 2011 WL 6303258, at *3 (D.N.J. Dec. 16, 2011) (citing *GlobespanVirata, Inc. v. Texas Instruments Inc.*, No. 03-cv-2854, 2005 WL 1638136, at *3 (D.N.J. July 12, 2015)). “The Court has great discretion in determining what kind of showing the moving party must make in order to satisfy the good cause requirement of [Rule 16].” *Baymont Franchise Sys., Inc. v. Bernstein Co., LLC*, No. 18-cv-620, 2020 WL 3287150, at *4 (D.N.J. June 17, 2020). However, generally the moving party must show that, “despite its diligence, the deadlines set forth in the scheduling order could not reasonably be met.” *Harbor Laundry Sales*, 2011 WL 6303258, at *3.

Defendants argue that, because the Motion was filed on December 20, 2022, the final day set in the original and amended scheduling order for “[a]mendments to the pleadings or to join other parties with leave of Court,” it must be evaluated only under Rule 15’s liberal standard. ECF No. 113 at 6; ECF No. 120 at 2-4. Plaintiffs argue in response that, because Defendants did not have leave of Court to file their Amended Answer by December 20, 2022, Defendants must establish good cause under Rule 16 prior to any analysis under Rule 15. ECF No. 117 at 5. In other words, Plaintiffs appear to argue that Defendants should have both filed the Motion *and* secured leave of Court for the filing of the Amended Answer prior to December 20, 2022.

The Court is not persuaded by Plaintiffs’ arguments. Rule 16 is typically employed where a party files a motion seeking leave to amend or to add new parties *after* the deadline set forth in the scheduling order has actually expired. *See Baymont*, 2020 WL 3287150, at *4 (applying Rule 16 standard where the motion to amend the answer was filed approximately four months after the deadline set forth in the pretrial scheduling order); *Miller v. Campbell Soup Co. Ret. & Pension Plan Admin. Comm.*, No. 19-cv-11397, 2022 WL 17555302, at *2 (D.N.J. Dec. 9, 2022) (applying Rule 16 standard where defendant sought leave to file an amended answer and to add an affirmative defense one week after the deadline set forth in the scheduling order). Accordingly, the Court will interpret the operative scheduling order (ECF No. 86) to permit the parties to submit motions for leave to amend the pleadings or to add new parties through December 20, 2022.¹ Rule 15 therefore governs the Motion.

¹ Other courts have also interpreted scheduling orders and applied the liberal pleading standard of Rule 15 rather than the more stringent Rule 16(b) standard. *See, e.g., Altana Pharma AG v. Teva Pharms. USA, Inc.*, No. 04-cv-2355, 2007 WL 9724442, at *3 (D.N.J. Mar. 29, 2007) (applying the Rule

B. Whether Defendants Unduly Delayed in Filing the Motion

As the Third Circuit has noted, “[t]he mere passage of time does not require that a motion to amend . . . be denied on grounds of delay.” *Cureton v. Nat’l Collegiate Athletic Ass’n*, 252 F.3d 267, 273 (3d Cir. 2001). Indeed, “delay alone is an insufficient ground to deny leave to amend.” *Id.* Only delays that are either undue or prejudicial warrant denial of leave to amend. *Geness v. Cox*, 902 F.3d 344, 364 (3d Cir. 2018). A court must “focus on the movant’s reasons for not amending sooner” in evaluating whether delay is undue or prejudicial. *Cureton*, 252 F.3d at 273.

Defendants argue that they base their proposed amendments on evidence only recently uncovered. ECF No. 113 at 7. Defendants state that they only received the relevant documents and privilege log sometime in August and September 2022 and that those documents, which numbered approximately 800,000 pages, took several months to review. *Id.* at 8; ECF No. 120 at 4-5. Finally, Defendants argue that their proposed amendments are also based on facts “which came to light as a result of Plaintiffs’ claim construction arguments” that were filed on October 28, 2022. ECF No. 113 at 8. Plaintiffs counter that Defendants’ proposed amendments are not based on recently uncovered evidence, but instead merely regurgitate defenses that Defendants first raised prior to the commencement of this action and defenses also raised in Defendants’ invalidity contentions. ECF No. 117 at 7. Even accepting Defendants’ argument that they only received the requisite information prior to filing the proposed Amended Answer in August or September 2022, Plaintiffs argue that Defendants have “wait[ed] until the last possible moment” to request leave to amend their Answer. *Id.*

The Court finds that there is no undue delay here. Although Plaintiffs are correct that there is approximately a four-month span of time between Defendants’ receipt of the earliest documents lending credence to their proposed amendments and the Motion, the Court cannot say that such delay was undue or prejudicial where Defendants represent that it took “a few months to review nearly 800,000 pages of documents.” ECF No. 120 at 4-5. The cases Plaintiffs cite in support of their argument that the Motion is untimely, namely *Genentech, Inc. v. Amgen Inc.*, No. 17-cv-1407, 2020 WL 708113 (D. Del. Feb. 12, 2020), and *Pfizer Inc. v. Sandoz Inc.*, No. 12-cv-654, 2013 WL 5934635 (D. Del. Nov. 4, 2013), are inapposite. ECF No. 117 at 9. In those cases, the moving parties waited several months to amend following the receipt of deposition testimony that would support the proposed amendments. *Genentech*, 2020 WL 708113, at *1; *Pfizer*, 2013 WL 5934635, at *4. Here, the parties’ dispute does not relate to deposition testimony which is known to each party at the

15 standard where the scheduling order listed “NONE” as the deadline to file motions to amend the pleadings, interpreting the scheduling order as not intending to bar such motions, and finding that defendants were not attempting to modify the terms of the scheduling order by filing their respective motions for leave to file amended answers).

time the testimony is given—rather, the parties’ dispute stems from the review of nearly 800,000 pages of documents and how quickly Defendants reviewed same prior to filing the Motion. Defendants also note that it was not until they reviewed those documents that they discovered non-public stability data concerning EXPAREL® and non-public, contradictory statements Plaintiffs made to the FDA and PTO that allegedly support the proposed amendments. ECF No. 120 at 5. Ultimately, the Court finds no undue delay here where Defendants filed the Motion just four months after receiving and reviewing nearly 800,000 pages of documents, three months after reviewing the relevant privilege log, and less than two months after Plaintiffs’ opening claim construction brief was filed, all of which allegedly contained information relevant to the proposed amendments.² *See Eisai Co., Ltd. v. Teva Pharms. USA, Inc.*, 247 F.R.D. 445, 449 (D.N.J. 2007) (holding that the court “cannot fault a party for waiting an extra couple of months to fully synthesize the information available to it before filing a motion to amend” where defendants had to review 80,000 pages of documents).

C. Whether Defendants’ Amendments Would Unduly Prejudice Plaintiffs

As it concerns prejudice, the Court must consider the hardship to Plaintiffs if Defendants’ Motion is granted. *Cureton*, 252 F.3d at 273. Specifically, the Court must consider whether granting the Motion “would result in additional discovery, cost, and preparation to defend against new facts or theories.” *Id.*

Defendants argue that granting the Motion will result in no prejudice to Plaintiffs as evidence relating to the inequitable conduct defense will “substantially overlap” with other discovery that will be produced. ECF No. 113 at 10. Indeed, Defendants note that the discovery already produced by Plaintiffs is relevant to its amendments as some of those documents were the catalyst for this very Motion. *See id.* Moreover, Defendants note that electronic discovery has not yet begun, depositions have not yet been taken, and fact discovery will remain open until March 17, 2023. *Id.* at 9.

Plaintiffs disagree. Plaintiffs argue that Defendants’ proposed amendments are vague as to the particular individuals who allegedly sought to deceive the PTO and as to whether any of those individuals had the “specific intent to deceive the PTO.” ECF No. 117 at 11. These vague allegations, Plaintiffs assert, will require “significant additional fact and expert discovery.” *Id.* Moreover, Plaintiffs argue that granting the Motion would delay resolution of this action because it would be impossible to conduct discovery relevant to the inequitable conduct defense within the current fact discovery deadline of March 17, 2023, and any extension to the

² Rule 16 does not apply here. Even applying the Rule 16 standard, however, the Court would find that Defendants have established good cause to amend the scheduling order for the same reasons the Court finds that Defendants were diligent and did not unduly delay in filing the Motion.

schedule would make it more difficult for the Court to render a decision in this action in advance of the 30-month stay. *Id.* at 12.

The Court agrees with Defendants that Plaintiffs will suffer no undue prejudice if the Motion is granted. In light of the substantial amount of discovery yet to be completed, including electronic discovery and depositions, the Court does not believe that discovery has progressed to such a late stage that permitting the amendment would be unduly prejudicial. Although the Court recognizes that the parties will no doubt expend additional resources in addressing the inequitable conduct counterclaim, there is significant overlap between this claim and the others asserted in this action—as Plaintiffs acknowledge (ECF No. 117 at 10-11)—meaning that the parties will not be starting discovery anew as to the claim.

Notably, the cases Plaintiffs cite in support of their argument of prejudice are distinguishable. For example, in *Pfizer Inc. v. Teva Pharms. USA, Inc.*, 803 F. Supp. 2d 409, 434 (E.D. Va. 2011), the court’s finding of prejudice was motivated largely by the fact that defendant’s second request to amend its answer was made while trial was ongoing. Here, fact discovery remains open, expert discovery has not been completed, and the parties are still more than 6 months from trial. In other words, Plaintiffs will have sufficient time to conduct discovery and prepare the action for trial.

It should be noted that Plaintiffs also argue that Defendants’ allegedly undue delay in bringing this Motion demonstrates bad faith and prejudice sufficient to warrant denial of the Motion. ECF No. 117 at 10. However, because the Court already found that there was no undue delay between Defendants’ receipt of the relevant documents and information necessary to submit the Motion and the filing of same, the Court rejects Plaintiff’s arguments.

D. Whether the Proposed Amendments are Futile

Turning next to Plaintiffs’ futility challenge, the Court notes that an amendment is futile if it “is frivolous or advances a claim or defense that is legally insufficient on its face.” *Harrison Beverage Co. v. Dribeck Imps., Inc.*, 133 F.R.D. 463, 468 (D.N.J. 1990) (citing 6 Wright, Miller & Kane, *Federal Practice & Procedure* § 1487 at 637-642 (2d ed. 1990)). To determine whether an amendment is insufficient on its face, the Court employs the standard applied to Rule 12(b)(6) motions to dismiss. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997). In other words, all allegations in the pleading must be accepted as true, all reasonable inferences must be drawn in favor of the moving party, and the court must determine if “under any reasonable reading of the [amended pleading], the [moving party] may be entitled to relief.” *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008) (quoting *Pinker v. Roche Holdings Ltd.*, 292 F.3d 361, 374 n.7 (3d Cir. 2002)). Against that backdrop, dismissal of a claim is appropriate only if the pleading does not set

forth “enough facts to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007).

In essence, this Court would have to decide a dispositive motion—a motion to dismiss the new counterclaim—in the context of a motion to amend Defendants’ Answer. “In the interests of judicial economy and in the absence of undue prejudice, the Court may decline to engage in a detailed futility analysis” where those arguments are better suited for consideration in a motion to dismiss. *See Colombo v. Bd. of Educ. for the Clifton Sch. Dist.*, No. 11-cv-785, 2016 WL 6403081, at *2 (D.N.J. Oct. 27, 2016); *In re Aetna UCR Litig.*, No. 07-cv-3541, 2015 WL 3970168, at *8 (D.N.J. June 30, 2015); *Travelers Casualty & Surety Co. v. Becton Dickinson & Co.*, No. 14-cv-4410, 2017 WL 349376, at *2 (D.N.J. Jan. 24, 2017); *S.M. & E.M. v. Freehold Reg’l High Sch. Dist. Bd. of Educ.*, No. 22-cv-107, 2022 WL 4226354, at *3 (D.N.J. Sept. 13, 2022).

That is precisely the case here. Having found that Defendants did not unduly delay in filing the Motion and having found that granting the Motion would not prejudice Plaintiffs, the Court declines to engage in a detailed futility analysis at this stage.

CONCLUSION

For the reasons set forth above;

IT IS on this 10th day of February 2023,

ORDERED that Defendants’ Motion is **GRANTED**; and it is further

ORDERED that Defendants shall file the Amended Answer by February 17, 2023; and it is further

ORDERED that because the Court considered documents that were filed under seal in issuing this Letter Order, the Letter Order shall initially be filed under seal. By February 24, 2023, the parties shall inform the Court, via a joint letter on the docket, if any portion of the Letter Order should remain under seal and the legal basis for doing so. If the Court does not receive any such submission, the Letter Order will be unsealed on March 3, 2023; and it is further

ORDERED that Plaintiffs shall file a response to the Amended Answer by March 3, 2023.



HON. JOSÉ R. ALMONTE
UNITED STATES MAGISTRATE JUDGE